DT07 Res CT/PTO 0 8 FEB 2005

#### PATENT APPLICATION

### N THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q85258

MIKOSHIBA, Imao, et al.

Appln. No.: 10/519,155

Group Art Unit: NOT YET ASSIGNED

Confirmation No.: NOT YET ASSIGNED

Examiner: NOT YET ASSIGNED

Filed: December 27, 2004

For:

DRUG COMPOSITION FOR PREVENTION OR INHIBITION OF ADVANCE OF

DIABETIC COMPLICATION

# INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §§ 1.97 and 1.98

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

One copy of each of the listed documents is submitted herewith, except for the following: U.S. patents and/or U.S. patent publications; and co-pending non-provisional U.S. applications filed after June 30, 2003.

The present Information Disclosure Statement is being filed: (1) No later than three months from the application's filing date; (2) Before the mailing date of the first Office Action on the merits (whichever is later); or (3) Before the mailing date of the first Office Action after

## INFORMATION DISCLOSURE STATEMENT

U.S. Appln. No.: 10/519,155

filing a request for continued examination (RCE) under §1.114, and therefore, no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

These are the references listed in the International Search Report. Some of the references are originally written in Japanese, so the corresponding US or EP patent application publication, or the Japanese original document with the abstract written in English is enclosed.

- (1) US2003/0040490 A1 (cited as X and Y).
- (2) EP1179342 A1 (cited as Y).
- (3) JP2000-26292 A (cited as Y); the full text is available only in Japanese, so the English abstract is enclosed.
- (4) Japanese Journal of Clinical Medicine, 1997, Special extra issue, Vol. 55, pp. 171-179 (cited as A); the full text and the abstract are available only in Japanese.
  - (5) Drugs of the Future, 2000, Vol. 20, No. 10, pp. 1034-1042 (cited as A).

### INFORMATION DISCLOSURE STATEMENT

U.S. Appln. No.: 10/519,155

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account. A duplicate copy of this paper is attached.

Respectfully submitted,

Registration No. 24,513

Peter D. Olexy

SUGHRUE MION, PLLC

Telephone: (202) 293-7060 Facsimile: (202) 293-7860

 $\begin{array}{c} \text{Washington office} \\ 23373 \\ \text{customer number} \end{array}$ 

Date: February 8, 2005

Substitute for Form 1449 A & B/PTO	omplete if Known		
	Application Number	10/519,155	
ON P E INFORMATION DISCLOSURE	Confirmation Number	NOT YET ASSIGNED	
STATEMENT BY APPLICANT	Filing Date	December 27, 2004	
0	First Named Inventor	MIKOSHIBA, Imao	
(use as many sheets as necessary)	Art Unit	NOT YET ASSIGNED	
	Examiner Name	NOT YET ASSIGNED	
Sheet 1 of 1	Attorney Docket Number	Q85258	

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.1	Document Number		Publication Date	
		Number	Kind Code <sup>2</sup> (if known)	MM-DD-YYYY	Name of Patentee or Applicant of Cited Docume
		US 2003/0040490	Al	02-27-2003	Sugiyama et al.
		US			

FOREIGN PATENT DOCUMENTS							
Examiner Cite Initials* No.1	Foreign Patent Document			Publication Date	Name of Patentee or	6	
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)	MM-DD-YYYY	Applicant of Cited Document	Translation <sup>6</sup>
		EP	1 179 342	A1	02-13-2002	Kissei Pharmaceutical Co., Ltd	English
		JP	2000-26292		01-25-2000	Kissei Pharmaceutical Co., Ltd.	Abstract
					_		
		<u> </u>					
				<u> </u>			
		ļ					
L		į					

NON PATENT LITERATURE DOCUMENTS				
Examiner Cite Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazin initials* No. journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where publisher.				
		Japanese Journal of Clinical Medicine, 1997, Special extra issue, Vol. 55, pp. 171-179	No	
		Drugs of the Future, 2000, Vol. 20, No. 10, pp. 1034-1042	English	
_				

	I	l l	
l		<b>I</b>	
		<b>I</b>	
E		I Date Constituted	
l Examiner Signature		Date Considered	
Ziraniniter Digitature	L	Date College	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kind Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or in the comment box of this document. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to indicate here if English language Translation is attached.